Sub C1

1. (Amended) A device for implanting autologous vascular smooth muscle cells transduced with a gene of interest [in a patient] into a mammalian subject, comprising:

a tubular elongate member having a wall, which wall has an interior surface, an exterior surface, and pores therein;

the autologous smooth muscle cells transduced with the gene of interest immobilized within the pores and upon the interior surface of the wall to form a tubular smooth muscle cell complex having an interior surface; and

autologous vascular endothelial cells adherent to the interior surface of the tubular smooth muscle cell complex.

B1

6. (Amended) A device as in claim 1, wherein the autologous vascular smooth muscle cells are transduced with a gene encoding granulocyte colony stimulating factor or granulocyte macrophage colony stimulating factor.

7. (Amended) A device as in claim 1, wherein the autologous vascular smooth muscle cells are transduced with a gene encoding Factor IX.

B2

8. (Amended) A device as in claim 1, wherein the transduced autologous vascular smooth muscle cells [constitutively] express an anticoagulant.

Sub C3

11. (Amended) A method for introducing a gene of interest [to a patient] into a mammalian subject, comprising:

engrafting a device as in claim 1 into the [patient's] subject's vascular system, wherein the transduced autologous vascular smooth muscle cells contain the gene operably linked to a promoter for expression.

B3

13. (Amended) A method as in claim 11, wherein the device is engrafted into the [p]atient's] subject's arterial system.

14. (Amended) A method for [treating anemia in a patient] delivering erythropoietin to a mammalian subject, comprising engrafting a device as in claim 1 into the [patient's] subject's vascular system, wherein the transduced autologous smooth muscle cells express erythropoietin.

15. (Amended) The method of claim 14, wherein the device is engrafted into the [patient's] subject's arterial system.

16. (Amended) A method for treating an occlusion of a blood vessel [in a patient] in a mammalian subject, comprising engrafting a device as in claim 1 into the occluded blood vessel bypassing the occlusion, wherein the transduced cells constitutively express an anticoagulant protein.

19. (Twice Amended) A method for delivering an insulin or proinsulin polypeptide to a [patient in need thereof] mammalian subject, comprising engrafting a device as in claim 1 into the [patient] subject, wherein the transduced cells constitutively express an insulin or proinsulin polypeptide.

20. (Amended) A method for [treating or preventing a disease in a mammal] delivering a protein product to a mammalian subject, comprising:

removing vascular endothelial cells and vascular smooth muscle cells from the [mammal] subject;

transducing the smooth muscle cells with a gene which encodes [a] the protein product [for treating or preventing the disease], operably linked to a promoter;

immobilizing on a tubular elongate porous vascular graft device the transduced smooth muscle cells within the pores and interior surface of the graft;

coating the interior of the graft device having immobilized thereon the transduced smooth muscle cells with the endothelial cells; and

engrafting the device having the immobilized transduced smooth muscle cells and endothelial cells into the vasculature of the [mammal to treat or prevent the disease] subject to deliver the protein product thereto.

21. (Amended) The method of claim 20, further comprising the step of cultivating the vascular smooth muscle cells obtained from the [mammal] subject in a medium containing autologous serum prior to immobilizing the cells on the vascular graft.

REMARKS

With entry of this amendment, claims 1-22 are pending in the application. By this amendment, claims 1, 6-8, 11, 13-16, and 19-21 have been amended for purposes of clarifying the subject matter of the claimed invention. In addition, an obvious typographical error has been corrected in the specification. All of the amendments presented herein are fully supported by the specification, and no new matter has been added to the application.

Patentability under 35 U.S.C. § 112

The Examiner has rejected all of Applicants' claims under 35 U.S.C. § 112, first paragraph, on the grounds that the